PI Information

This survey is for UWL faculty, staff, and students to seek an exempt status designation for a research project involving human subjects. While this survey is accessible to individuals that are currently not affiliated with UWL, exemptions are only valid if requested by and granted to a current UWL employee or currently enrolled UWL student.

Students must have mentor/advisor approval before using this tool.

Exclusions: you may <u>not</u> use this Exempt Decision Tool if any of the following are true:

- Certain participant incentives are being offered (e.g., financial; variable).
- Other institutions will be relying on UWL's IRB to provide review and oversight.
- Any research that involves vulnerable populations (e.g., individuals under 18; prisoners).
- Exemption is being claimed under exemption research categories numbered 45 CFR 46.104(d): 4(c), 4(d), 5, 7, and/or 8.

Prior to completing this survey, you should review UWL's Researcher's Guide for Submission of Protocols, which is located on <u>UWL's IRB website</u>, to ensure that your research meets the definition of exemptible research.

You will need the following information available to complete the survey:

- Names and email addresses of any advisors, mentors, or co-PI/PDs.
- IRB training completion certificate(s) from a UWL approved course for you, your primary mentor, primary thesis committee advisor, any co-PI/PDs, and/or personnel (collated into a single pdf with your certificate listed first).
- Project title and basic information about the research project.
- An Informed Consent Form and Debriefing Form may also be required.

If you have any questions or concerns about this survey, please contact the IRB office at irb@uwlax.edu.

What is your name and email address?



Last Name Email address

Please select one of the following.

- O Faculty/Staff
- O Graduate Student
- O Undergraduate Student
- O Doctoral Candidate

Will this study include participant incentives for research subjects? This does NOT include reimbursements (e.g., travel & lodging).

O Yes

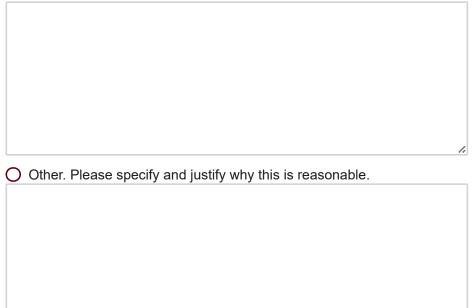
O No

What type(s) of participant incentives are being provided?

O Financial incentives (e.g., gift card, cash).

O Variable incentives (i.e., a combination of incentive types and/or amounts).

O Course-related extra credit and/or course credit that is reasonable (e.g., not more than 15 points or less than 5% of a student's grade). Indicate the amount of extra credit and/or course credit below and justify why this is reasonable.



If a student opts NOT to participate in the course-related research, is there a non-research alternative that would take the student similar time/effort to obtain credit/extra credit?

Note: Non-research alternatives MUST be explained in the informed consent.

O Yes

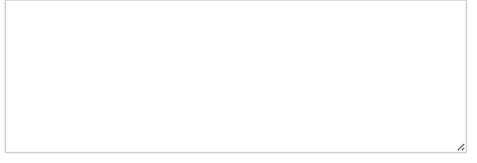
O No

Are the research activities in which participants will take part occurring on one occasion or during multiple occurrences?

Note: For research activities participants would take part in on multiple occasions, the incentives should also be spread out over time (e.g., two points of extra credit awarded per testing day). No more than 50% of the total incentives should be used as a completion bonus for participants that take part in the entirety of the research. The distribution of incentives MUST be explained in the informed consent.

O Occurring on one occasion (e.g., one-time survey, interview, intervention).

O Multiple occurrences (e.g., multiple surveys or testing days across days/weeks/months). Provide information about how you will do this below.



Will this study include multiple research sites and/or PI(s) outside of UWL for which Reliance Agreements will be required? (If you are not sure, review the Researcher's Guide and/or check with the IRB office.)

 \checkmark

O Yes

O No

What department or office is this research being conducted for?

For the question above, you selected "other". For which department or office is this research being conducted?

Are there other individuals (faculty, staff, or students) who should be listed as co-PI/PDs on this project?

A PI/PD, or principal investigator/project director, is a person responsible for the research project. Duties of a PI/PD could include preparing the protocol, conducting research, analyzing data, and reporting results.

Students: do **not** include your advisor(s) or thesis committee members here, unless they would otherwise qualify as a PI/PD (see definition above). If they are acting only in a mentoring or advisory capacity, they should be listed in later questions about advisors.

O Yes

O No

How many co-PI/PDs do you have?

List the name, status (faculty/staff, grad student, or undergrad), email address, and affiliation of your co-PI/PD(s). Complete one row per co-PI/PD; it is acceptable to have blank rows.

	First Name	Last Name	Faculty/Staff, Grad Student, Undergraduate, or Non-UWL	Email address	Affiliation (UWL or list other)
Co-PI/PD #1					
Co-PI/PD #2					
Co-PI/PD #3					
Co-PI/PD #4					
Co-PI/PD #5					

Are there other individuals (faculty, staff, or students) who will be personnel on this project? (Do not include thesis committee advisors.)

O Yes

O No

How many personnel do you have? (Do not include thesis committee advisors.)

List the name, status (faculty/staff, grad student, or undergrad), email address, and affiliation of your personnel. Complete one row per person; it is acceptable to have blank rows.

	First Name	Last Name	Faculty/Staff, Grad Student, Undergraduate, or Non-UWL	Email Address	Affiliation (UWL or list other)
Personnel #1					
Personnel #2					
Personnel #3					
Personnel #4					
Personnel #5					

List the name, status (faculty/staff, grad student, undergrad, or non-UWL), email address, and affiliation (UWL or other institution) of any additional co-PI/PDs not listed in the previous question.

List the name, email address, and affiliation of your primary advisor, co-advisors, and thesis committee members. You must have a lead advisor; however, the other rows should be left blank if you do not have co-advisors or a thesis committee.

1.

	First Name	Last Name	Email Address	Affiliation (UWL or list other)
Lead Advisor				
Co-Advisor / Thesis Committee Member #1				
Co-Advisor / Thesis Committee Member #2				
Co-Advisor / Thesis Committee Member #3				
Co-Advisor / Thesis Committee Member #4				

Have you discussed the project with your Mentor(s)/Advisor(s) and/or, if applicable, your Thesis Committee? Reminder: in addition to discussing this project with your mentor/advisor, you must have

their approval to submit to the IRB using this Exempt Decision Tool.

O Yes

O No

Please follow up with a discussion of your research in a meeting with your Advisor and then complete the decision tool. By clicking next, you will be sent to the end of the survey. You may complete it again should you and your Advisor determine that seeking an exempt designation for your project is appropriate.

Training

Have you, any faculty/staff mentor(s), co-PI/PDs, personnel, and your primary thesis committee advisor (as applicable) completed one of the UWL-approved IRB Online Training Courses?

The approved courses are the following, as applicable to the proposed research type, from CITI Human Subjects Research:

- Biomedical Research Investigators
- Social & Behavioral Research Investigators
- · Research with data or laboratory specimens ONLY
- IRB Members
- O Yes

O No

Please upload one (1) PDF document of the certificate(s) of completion for the mandatory IRB Online Training Course for the following individuals as applicable in the order listed below:

- 1. Your certificate
- 2. Faculty/staff mentor(s) at minimum the Primary mentor, as applicable
- 3. Co-PI/PD(s)
- 4. Personnel
- 5. Primary thesis committee advisor

Note: The system will only accept one document, which must contain all required certificates.

Please go to <u>UWL's IRB website</u> for directions on registering for and completing the required training. By clicking next, you will be sent to the end of the survey. You may complete it again should you and, if

applicable, your Advisor determine that seeking an exempt designation for your project is appropriate.

Title IX Confidentiality Exclusions

Will your research gather information about sex discrimination?

Sex discrimination includes sexual harassment, sexual violence, sex-based misconduct, relationship violence, discrimination based on pregnancy, and the failure to provide equal opportunities in employment, admissions, or any educational programs or activities (Title IX of the Education Amendments of 1972 [20 U.S.C. § 1681]).

O Yes

O No

All postsecondary employees conducting research to gather information about sex discrimination must complete additional *annual* Confidential Employee Status Training from the Title IX Office. In addition to UWL faculty/staff, this includes student employees and outside collaborators from other postsecondary institutions. For information about the training, contact UWL's Title IX Office: https://www.uwlax.edu/title-ix/.

Upload a single PDF copy of all applicable training completion certifications.

NOTE: This does include Primary mentors on protocols, but not necessarily all Thesis Committee members.

1.

Summary

What is the title of your project?

Does the research project include any of the following? Check all that apply.

Illegal activities (e.g., underage drinking, illegal substances)

International activities, collaborator(s), or funding

Vertebrate animals (e.g., dogs)

Biological, recombinant, and/or hazardous chemical materials (e.g., blood, saliva, tissues, cells)

- Student information (e.g., grades, demographics)
- Exercise beyond routine daily movement
- None of the Above

Provide a 1-2 sentence overview about your research project and how human subjects are involved (e.g., research topic/question, demographic information).

Briefly describe the procedures and/or activities that research subjects will undergo as part of this study if applicable. Include the following information as needed:

- Types of survey/interview questions being asked
- Types of observations being conducted, including where observations will take place and how they will be recorded (e.g., field notes, video)
- Types of interactions or interventions subjects will undergo (e.g., watching videos, completing puzzles, sampling food)
- Types of tests conducted (e.g, memory test)

Briefly describe any other data from participants you are using for your project if applicable (e.g., IRAP data, test grades, public voting records, social media posts). Otherwise indicate "not applicable."

When will the data be collected or obtained? Provide the start and end dates for data collection or acquisition below.

 Start date (mm/dd/yyyy)

 End date (mm/dd/yyyy)

Will you be asking participants to answer survey or interview questions about sensitive topics (e.g., trauma, assault, suicide, mental illness) or exposing them to information about sensitive topics (e.g., they read a story about an assault)?

O Yes

O No

Describe how you will do both of the following:

- Warn participants about this potentially emotionally distressing content in your informed consent AND
- Provide them with contact information for relevant mental health/support resources in case participants have a negative emotional reaction (e.g., debriefing form).

Upload a single PDF including the following information:

- 1. Questions the researcher(s) will be asking or the information participants will be exposed to
- 2. Copy of the contact information for relevant mental health/support resources

Refer to the <u>Debriefing Template for Off-Campus Resources</u> for an example.

Does your research include human subjects as defined below?

A human subject is a living individual about whom an investigator conducting research obtains one or more of the following:

1. identifiable private information;

- 2. data through intervention or interaction with the individual (e.g., online surveys, interviews, clinical studies); and/or
- 3. identifiable biospecimens.
- O Yes
- O No

Secondary Research

Will you be conducting secondary research (i.e., research on data that already exists that was collected or developed for a purpose other than your proposed study)? This includes but is not limited to data obtained from Institutional Research, Assessment, & Planning (IRAP), test grades, public voting records, public social media posts, and data repositories.

O Yes

O No

Are the data anonymous or de-identified by the researcher(s)?

Note: "Anonymous" means that there is no link, direct or indirect, between the data and the participants' identifiable information. "Deidentified data" has personally identifying information permanently removed from the data file. If there is a code that links the data to the participants, then these criteria are not met.

O Yes

O No

Are the secondary data publicly available?

NOTE: Publicly available means the data are accessible to anyone in the general public without the need for special permission or privileges.

O Yes

O No

Are you transcribing/coding the secondary data in such a way that participants' identities cannot be ascertained (e.g., copying former students' grades into a data file with no identifying information or code linking the data to individual students)?

O Yes

O No

Will you be contacting the participants as part of this study related to the secondary data (e.g., survey questions, interviews)?

O Yes

O No

Will you try to re-identify participants from de-identified data?

O Yes

O No

Will you be conducting primary/new research (research that you will conduct to collect data)?

O Yes

O No

Please "sign" your IRB Exemption Request Form.

Your UWL person ID number will be one of the following:

- for UWL faculty / staff your 8-digit person ID number; it is found on your pay statement and begins with 00
- for UWL students your 9-digit student ID number

I have read the appropriate content from <u>UWL's IRB website</u>, and to the best of my knowledge, the information provided in this IRB Exemption Request Form is complete and correct.

First name	
Last name	
UWL Person ID number	
Today's date	

Basic Research Design

Will the human subjects be over the age of 18 and/or classified as an emancipated minor?



Could disclosure of participants' responses place them at risk of criminal or civil liability OR be damaging to their financial standing, employability, educational advancement, or reputation?

Note: Examples include asking participants to report on their own illegal activity, course grades, levels of prejudice, views about their employer, sexual behavior, or personal medical information.

O Yes

O No

What procedures will you put in place while collecting data to maintain confidentiality and protect participants' privacy? Review carefully and check all that apply:

 Having participants give oral rather than written, signed consent Not collecting any personally identifying information from participants Not audio or video recording participants Transcribing recorded data and destroying recordings as soon as possible Collecting minimal demographic data using only broad categories to reduce the potential of being able to identify participants from such data Verifying that an online survey is not recording IP addresses (e.g., checking "anonymize responses" in Qualtrics) 	Using number codes or pseudonyms rather than names when recording data
 Not audio or video recording participants Transcribing recorded data and destroying recordings as soon as possible Collecting minimal demographic data using only broad categories to reduce the potential of being able to identify participants from such data 	Having participants give oral rather than written, signed consent
 Transcribing recorded data and destroying recordings as soon as possible Collecting minimal demographic data using only broad categories to reduce the potential of being able to identify participants from such data 	Not collecting any personally identifying information from participants
Collecting minimal demographic data using only broad categories to reduce the potential of being able to identify participants from such data	Not audio or video recording participants
participants from such data	Transcribing recorded data and destroying recordings as soon as possible
Verifying that an online survey is not recording IP addresses (e.g., checking "anonymize responses" in Qualtrics)	
	Verifying that an online survey is not recording IP addresses (e.g., checking "anonymize responses" in Qualtrics

Transferring data (from person to person or place to place) promptly and securely

- Deleting identifiers as soon as possible
- Uploading data promptly to encrypted servers
- Other must describe other procedures if no boxes above are checked

What procedures will you put in place to securely store the data to maintain confidentiality and protect participants' privacy? Review carefully and check all that apply:

1.

- Storing hardcopies in locked cabinets/rooms
- Storing data on encrypted computers/servers and/or password-protected devices
- Storing data, master code lists, and completed informed consents in separate, secure locations

Limiting access to identifiable data to as few researchers as possible

Other - must describe other procedures if no boxes above are checked

	1.

Your informed consent for research participants must include the following:

- Statement about how a breach in confidentiality is a potential risk of participating in this study, and what the risk of a potential breach would be (e.g., criminal or civil liability, damage to reputation or employability)
- Statement about how you are protecting the confidentiality of participants using the methods described above

Upload your informed consent document as a single PDF to demonstrate you have included these statements.

Will this research be conducted in a classroom setting?

O Yes

O No

Will this project interrupt learning ability? (e.g., disrupting the ability to learn for students attending class)

O Yes

O No

Does your research involve any of the following?

Educational tests

Survey procedures

- Interview procedures
- Observation of public behavior
- None of the above

Will there be interventions during this research? For example, asking them to do one of the following:

- complete a puzzle under noisy conditions;
- split a nominal amount of money between two people;
- perform a physical task; and/or
- solve a problem.

O Yes

O No

Will these interventions be physically invasive or involve the collection of bodily specimens (e.g., blood draw, saliva swab, urine sample)?

O Yes

O No

Will the researcher obtain the participants' informed consent prior to the intervention?

O Yes

O No

Are you asking participants to provide responses in this study in one of the following ways?

- Verbal
- Written
- Typed responses
- Audio/visual recordings of responses

NOTE: If you are only observing participants in a public setting and taking written notes, select 'No.'

O Yes

O No

Does the intervention meet ALL of the following criteria:

- Harmless
- Painless
- Has no lasting impact on the participants
- The participants are not likely to find the intervention offensive or embarrasing

O Yes

O No

Are subjects being deceived about the purpose of the research?

O Yes

O No

Will the participants be informed that they will be unaware of, misled, or deceived regarding the nature or purpose of the research as part of the consent process?

O Yes

O No

FDA Requirements

Will the project utilize biospecimens?

O Yes

O No

Does one or more of the following apply to all of the biospecimens that will be used for the project?

- are human cell lines obtained from a commercial provider;
- are human cells about which all information has been published;
- are unidentifiable biospecimens/information obtained from a commercial provider; and/or
- are unidentifiable biospecimens/information obtained from a provider that is prohibited from releasing identifiers by established regulations or policies.

O Yes

O No

Were/are the biospecimens recorded anonymously?

O Yes

O No

Does the biospecimen data/information have a code linking it to identifiable, private information of living individuals?

- O Yes
- O No

Can the researcher readily ascertain the identities of the individuals to whom the biospecimens/information pertain? Examples of when the researcher **cannot** link the data to living individuals include:

- the key to decipher the code is destroyed before research begins;
- researchers and the holder of the key to the code enter into an agreement preventing the release of the key to researchers under any circumstances; and/or
- there are IRB-approved written policies and/or legal requirements prohibiting the release of the key under any circumstances.
- O Yes
- O No

Does the project involve the use of food? (e.g., taste-testing, nutritional testing, dietetics)

- O Yes
- O No

Will the food used in the research be FDA qualified?

- O Yes
- O No

Dissemination

Is there a potential that you will share your data from this project (e.g., sharing with other researchers, uploading to an open science or data sharing repository, submitting to a journal with an accepted paper, presenting at a conference)?

NOTE: Deidentified data has personally identifying information permanently removed from the data file.

- O Yes De-identified Data
- O Yes Data with Identifiers

- Make sure that your consent form DOES NOT indicate that the data will only be accessible to the study researchers.
- Add a line to your consent form that says something to the effect of the following: "De-identified data may be shared with other researchers or made accessible to research journals and/or data sharing repositories. De-identified data has personally identifying information permanently removed from the data file."

Federal Funding

Is the project being supported by a federal department or agency directly or indirectly?

O Yes

O No

Which federal department or agency is supporting the project? Check all that apply.

ED, including McNair and Student Support Services
NASA, including Wisconsin Space Grant Consortium (WSGC)
NIH
NSF, including WiscAMP
Other PHS (not NIH, but including HRSA, SAMHSA, etc.)
Other (please specify)

Generative AI

Will you be using generative artificial intelligence (AI) tools when conducting this research? This includes use of an AI tool for any of the following:

- Analysis
- Transcription
- Obtaining data
- · Interaction with subjects
- Other uses

Will the AI tool have access to data you are collecting from research participants as part of your study (e.g., interview or survey responses, chat sessions between participants and AI tool)?

O Yes

O No

Describe below how the confidentiality of the participant data will be maintained including:

- What AI tool(s) you will be using and how you are using the AI tool(s).
- How you will maintain confidentiality (e.g., remove personally identifying information from the dataset/interviews before submitting to the AI tool(s); ensure the data submitted to the AI tool(s) does not become part of the AI's dataset/database of information).

Research participants should be notified in a consent document how their data will be used by the Al tool(s), what data the tool(s) will have access to, what the tool(s) will do with the data, and if the data can be removed from the tool(s).

NOTE: You will likely need to review the AI tool(s) terms of use and privacy policies. <u>Murphy Library</u> offers resources to start this process.

Additional Materials & Signature

Any additional materials must be uploaded as a single pdf document. This could include:

- If you are considering conducting your research at a third-party organization (e.g., local business; K-12 school), please upload your letter of support from this organization here.
- Optional: You may also choose to upload any additional materials about your project that you wish to be part of the record or that you would like reviewed. This could include sample interview questions, marketing materials, informed consent documents, etc. If you were already required to upload these materials, please do not submit duplicates here.

Please "sign" your IRB Exemption Request Form.

Your UWL person ID number will be one of the following:

- for UWL faculty / staff your 8-digit person ID number; it is found on your employee ID and pay statement and begins with 00
- for UWL students your 9-digit student ID number

I have read the appropriate content from <u>UWL's IRB website</u>, and to the best of my knowledge, the information provided in this IRB Exemption Request Form is complete and correct.

First name
Last name
UWL Person ID number
Today's date (mm/dd/yyyy)

Powered by Qualtrics